UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/646,763	10/24/2000	Michel Lanquetin	GEI-078	8985

7590 04/08/2004

Bierman Muserlian and Lucas
600 Third Avenue
New York, NY 10016

EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 04/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 03262004

Application Number: 09/646,763
Filing Date: October 24, 2000
Appellant(s): LANQUETIN ET AL.

Charles A. Muserlian
475 Park Avenue South
New York, N.Y. 10016
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed November 25, 2003.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1, 3, and 5-18 stand or fall together.

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct.

(9) Prior Art of Record

6,010,716	Saunal et al.	1-2000
5,290,769	Eibl et al.	5-1994
WO95/30409	Winters et al.	11-1995
EP 0 785 211	Maillo et al.	7-1997

Gennaro et al., Remingtons Pharmaceutical Sciences, 1990, page 1305

Merck Index, 12th edition, 1996, pages 889-890, Monograph 5232

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1, 3, 5-8, 11, 12, 14-15, and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunal et al. (WO96/30000, English equivalent: USPN 6,010,716 is also provided), reference of record, and Maillo et al. (EP 0 785 211 A1) in view of Winters et al. (WO95/30409), reference of record.

Saunal et al. teaches a transdermal topical formulation employing a solvent, absorption promoting agent, an active, comprising the steroid, nomegestrol, and a film-forming agent. Saunal et al. teaches the composition may contain 0.1 to 20.0% of nomegestrol (See col. 5, line 28). Saunal et al. also teaches the solvent or solubilizing

agent may be ethanol or isopropanol(See col. 7, line 13). Sanual et al. also teaches that the weight ratio of the ethanol may be 44% to 84.9% (See particularly col. 7, line 41-46). The film-forming agent is a cellulose derivative, hydroxypropylmethylcellulose, hydroxypropylmethylcellulose succinate acetate, and ethylcellulose. (See col.3, line 58-63). The film-forming agent of Saunal et al. can also be PVP VA, a known polyvinylpyrrolidone derivative (See col. 3, line 67).

Maillo et al. teaches a gel formulation for topical use containing progesterone compounds encompassed nomegesterol, with 20 to 40% of ethyl alcohol, 1 to 4% of polyethylene glycol, and water (See page 9, line 41; also page 18, line 25-40, Example 22).

The references do not expressly teach the amount of nomegestrol as 0.05 to 1% in the composition. The references do not expressly teach film-forming agent as methacrylates, and cellulose. The references do not expressly teach a plasticizing agent such as Labrasol®, a preferred C_8/C_{10} polyoxyethylene glycosyl glyceride herein. The references do not expressly teach the ratio of water, ethanol, propylene glycol, and Labrasol in preferred the solvent system herein. The references do not expressly teach a method of employing the topical nomegestrol composition to treat progesterone deficiency in a host.

Winters et al. teaches a topical formulation of the steroid, 19-nor progesterone for systemic delivery of active. The formulation has a solvent which may include alcohols (See page 4, line 1-2), film-forming agent such as methacrylates, and cellulose (See

page 4, line 8-11), a plasticizing agent such as Labrasol (See page. 4, line 18), and a penetration enhancer.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the amount of nomegestrol herein and a film-forming agent such as methacrylates and cellulose, and Labrasol into the nomegestrol topical composition of Saunal et al. It would have been obvious to one of ordinary skill in the art at the time the invention was made to adjust the ratio of water, ethanol, propylene glycol, and Labrasol in preferred the solvent system herein.

The employment of nomegestrol as an active agent in a topical pharmaceutical composition with carrier materials herein is motivated because these carrier materials, such as methacrylates and cellulose, and Labrasol, are known pharmaceutical excipients, known to be useful in substantially similar topical pharmaceutical compositions comprising the same and similar active ingredients. The incorporation of known carrier materials into a pharmaceutical composition containing a known active is considered within the skill of the artisan.

The optimization of result effect parameters (e.g., amounts of ingredients) is obvious as being within the skill of the artisan, absent evidence to the contrary. Amounts of composition ingredients employed herein are substantially similar to the prior art.

The instant composition containing nomegestrol would be reasonably expected to be similarly useful to raise progesterone levels in a host, regardless of their status as being menopausal or premenopausal, and treating progesterone deficiency thereby.

Claims 9-10, 13, 16, and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Saunal et al. and Maillo et al. in view of Winters et al. as applied to claims 1, 3, 5-8, 11, 12, 14-15, and 18 above, and further in view of Merck Index (Budavari et al., editor, Merck Index, 12th ed., 1996: page889-890, Compound 5232), Eibl et al. (USPN 5,290,769), and Remington's Pharmaceutical Sciences (Gennaro et al., Remington's Pharmaceutical Sciences, 18th ed., 1990: page 1305), reference of record.

The combination of Saunal et al., Maillo et al., and Winters et al. does not expressly teach the employment of isopropylideneglycerol, copolymer of methacrylic acid and ethyl acrylate, and carbomer in the topical nomegestrol composition. The combination of Saunal et al., Maillo et al., and Winters et al. does not expressly teach the ratio of propylene glycol and isopropylidene glycerol.

The Merck Index teaches that isopropylidene glycerol may be used as a solubilizing or plasticizing agent in pharmaceutical compositions (See page 889-890, Compound 5232).

Eibl et al. teaches the use of copolymer of methacrylic acid and ethyl acrylate as pharmaceutical auxiliary agents in topical formulation (See col 5, line 66 and col. 6, line 19-20).

Remington's Pharmaceutical Sciences teaches that carbomer is useful as a gelling and emulsifying agent in pharmaceutical compositions (See page 1305, col. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate isopropylideneglycerol, copolymer of methacrylic acid and ethyl acrylate, and carbomer into the topical nomegestrol composition.

One of ordinary skill in the art would have been motivated to incorporate isopropylideneglycerol, copolymer of methacrylic acid and ethyl acrylate, and carbomer into the topical nomegestrol composition since isopropylideneglycerol, copolymer of methacrylic acid and ethyl acrylate, and carbomer are known as agents for topical pharmaceutical excipients. Incorporating any known excipients, including isopropylideneglycerol, copolymer of methacrylic acid and ethyl acrylate, and carbomer, into the topical nomegestrol composition would be considered as being within the purview of skilled artisan. Furthermore, the optimization of the amount ratio between propylene glycol and isopropylidene glycerol would be obvious as considered being within the purview of skilled artisan.

(11) Response to Argument

Appellant's arguments in page 4 bridging page 5, first paragraph averring the cited prior art's failure to provide motivation to combine the teachings of the cited prior arts are not convincing. The herein claimed invention is drawn to a topical transdermal composition of nomegestrol, a solvent system, and optionally a diluent. The cited prior arts as a whole teaches a composition of nomegestrol useful for transdermal delivery of the same. Such composition is useful in combination with the herein claimed ingredients such as alcohols, methacrylates, and Labrasol®. The incorporation of

known carrier materials, such as herein claimed, into a pharmaceutical composition containing a known active, i.e., nomegestrol, is considered within the skill of the artisan.

Appellant's arguments averring the difference between transdermal dosage form and gel with systemic delivery of the drug are not convincing. The transdermal system Appellant described in page 5 of the appeal brief is a sustained release transdermal product, which usually have backing and drug reservoir for prolonged period of drug release. This is only one of the transdermal system known in the art. However, giving the broadest reasonable interpretation of the claim, the examiner considers any composition that delivers active agent through the dermal layer, i.e., skin, is transdermal composition. Such composition could be gel, cream lotion, lipstick, electrophoresis device, and etc. As long as the device or drug delivery system is capable of delivering drug systemically through dermal layer, it is a transdermal composition. In view of this, Saunal and Maillos teach a transdermal and gel composition that contain nomegestrol, the active compound herein claimed. Possessing the teachings of the cited prior arts as a whole, one of ordinary skill in the art would have been motivated to incorporate other well-known topical excipients, including the herein claimed ingredients, into the nomegestrol-containing transdermal composition.

Appellant's arguments averring Winters not overcome the deficiencies of the primary references are not convincing. Winters teaches the herein claimed excipients as useful in formulating topical composition. Taken the teachings of Winters, Saunal and Maillos together, one of ordinary skill in the art would have been motivated to

incorporate well-known topical excipients into nomegestrol-containing composition suggested by Saunal and Maillo, absent evidence to the contrary.

In view of the above, the examiner believes that the outstanding rejections should be sustained.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

San-ming Hui
Patent Examiner
Art Unit 1617
March 26, 2004

Conferees

BIERMAN MUSERLIAN AND LUCAS
600 THIRD AVENUE
NEW YORK, NY 10016

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER